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U.S. Serial No.: 10/667,151 Group Art Unit 1611

Examiner Charlesworth Rae

## **CLAIMS:**

- 1. (Original) An injectable formulation comprising: (a) a chemical ablation agent in an amount effective to cause tissue necrosis, and (b) a biodisintegrable viscosity adjusting agent in an amount effective to render the formulation highly viscous, wherein said injectable formulation is a sterile injectable formulation.
- 2. (Original) The injectable formulation of claim 1, wherein said ablation agent is an osmotic-stress-generating agent.
- 3. (Original) The injectable formulation of claim 1, wherein said ablation agent is an organic ablation agent.
- 4. (Original) The injectable formulation of claim 1, wherein said ablation agent is ethanol.
- 5. (Original) The injectable formulation of claim 1, wherein said ablation agent is a salt.
- 6. (Original) The injectable formulation of claim 1, wherein said ablation agent is sodium chloride.
- 7. (Original) The injectable formulation of claim 1, wherein said viscosity adjusting agent is present in an amount effective to provide a kinematic viscosity ranging from 5,000 cps to 100,000 cps.
- 8. (Original) The injectable formulation of claim 1, wherein said viscosity adjusting agent is present in an amount effective to provide a kinematic viscosity ranging from 10,000 cps to 50,000 cps.

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- 9. (Original) The injectable formulation of claim 1, wherein said viscosity adjusting agent comprises a polysaccharide.
- 10. (Original) The injectable formulation of claim 9, wherein said viscosity adjusting agent is a polysaccharide selected from methylcellulose, hydroxyethylcellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, methylhydroxyethylcellulose, methylhydroxypropylcellulose, carboxymethyl cellulose and its salts, hydroxyethylcarboxymethylcellulose and its salts, carboxymethylhydroxyethylcellulose and its salts, alginic acid and its salts, hyaluronic acid and its salts, carageenan, chitosan, xanthan gum, guar gum, gum arabic, gum karaya, gum ghatti, konjac and gum tragacanth.
- 11. (Original) The injectable formulation of claim 1, wherein said viscosity adjusting agent comprises a polypeptide.
- 12. (Original) The injectable formulation of claim 11, wherein said viscosity adjusting agent is selected from gelatin and collagen.
- 13. (Original) The injectable formulation of claim 1, wherein said viscosity adjusting agent is selected from carboxyvinyl polymer, polyvinylpyrrolidone, polyacrylic acid, polyacrylamide, polyacilic acid/acrylamide copolymer, polyethylene oxide, polypropylene oxide, poly(ethylene oxide-propylene oxide), polymetaphosphate, polyethyleneamine, polypyrridine, as well as salts thereof.
- 14. (Original) The injectable formulation of claim 1, further comprising an imaging contrast agent.

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- 15. (Original) The injectable formulation of claim 14, wherein the imaging contrast agent is an MRI imaging contrast agent.
- 16. (Original) The injectable formulation of claim 14, wherein the imaging contrast agent is an ultrasonic imaging contrast agent.
- 17. (Original) The injectable formulation of claim 16, wherein the ultrasonic imaging contrast agent comprises a plurality of solid particles.
- 18. (Original) The injectable formulation of claim 17, wherein the plurality of solid particles is selected from calcium carbonate particles, hydroxyapatite particles, silica particles, poly(lactic acid) particles, and poly(glycolic acid) particles.
- 19. (Original) The injectable formulation of claim 1, wherein said injectable formulation comprises a plurality of viscosity adjusting agents.
- 20. (Original) The injectable formulation of claim 1, wherein said injectable formulation comprises a plurality of ablation agents.
- 21. (Original) The injectable formulation of claim 1, wherein said injectable formulation further comprises a liquid selected from water and an organic solvent.
- 22. (Withdrawn) A method of treatment comprising injecting the injectable formulation of any of claims  $1\frac{1}{4}21$  into the tissue of a subject.
- 23. (Withdrawn) The method of claim 22, wherein said tissue is prostatic tissue.

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- 24. (Withdrawn) The method of claim 23, wherein said subject has been diagnosed with benign prostatic hypertrophy.
- 25. (Withdrawn) The method of claim 23, wherein the injectable formulation is transrectally injected into the subject.
- 26. (Withdrawn) The method of claim 23, wherein a plurality of injections are performed concurrently with a non-invasive imaging technique.
- 27. (Withdrawn) A prostatic ablation formulation comprising a prostatic ablation agent selected from free-radical generating ablation agents, oxidizing ablation agents and tissue fixing ablation agents.
- 28. (Withdrawn) The prostatic ablation formulation of claim 27, wherein the injectable prostatic formulation comprises a free-radical generating ablation agent.
- 29. (Withdrawn) The prostatic ablation formulation of claim 28, wherein the free-radical generating ablation agent is a peroxide compound.
- 30. (Withdrawn) The prostatic ablation formulation of claim 27, wherein the injectable prostatic formulation comprises an oxidizing ablation agent.
- 31. (Withdrawn) The prostatic ablation formulation of claim 27, wherein the injectable prostatic formulation comprises a tissue fixing ablation agent.
- 32. (Withdrawn) The prostatic ablation formulation of claim 31, wherein the tissue fixing ablation agent is selected from formaldehyde and glutaraldehyde.

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- 33. (Withdrawn) A system for the chemical ablation of tissue, said system comprising:
- (a) an injectable formulation comprising: (i) a chemical ablation agent in an amount effective to cause tissue necrosis, and (ii) a biodisintegrable viscosity adjusting agent in an amount effective to render the formulation highly viscous; and
  - (b) an apparatus for transcutaneously inserting said dosage form into said tissue.
- 34. (Withdrawn) The system of claim 33, wherein the apparatus is configured to insert said dosage form into the tissue transrectally.
- 35. (Withdrawn) The system of claim 33, wherein the tissue is prostatic tissue.
- 36. (Withdrawn) The method of claim 22, further comprising injecting a crosslinking agent into said tissue in an injection step separate from the injection of said injectable formulation.
- 37. (Withdrawn) The method of claim 36, wherein said crosslinking agent is injected subsequent to the injection of said injectable formulation.
- 38. (Original) The injectable formulation of claim 1, wherein said injectable formulation comprises an ionically crosslinkable polymer.
- 39. (Original) The injectable formulation of claim 38, wherein said ionically crosslinkable polymer is an alginate polymer.